CHAPTER 3

RISK ASSESSMENT DATA NEEDS AND TASKS DURING THE REMEDIAL INVESTIGATION

Project Management Guidelines. Remedial project managers will establish the schedule of submission for the deliverables for the RI Reports and Baseline Risk Assessment Reports. The schedule may vary from site to site, as appropriate. Interested parties (States, Commonwealths, tribes and other stakeholders) may be involved in the scheduling and review process, as appropriate. Refer to your regional office for guidance regarding the order of the deliverables. These deliverables should also be defined in the Workplan.

General RI Guidelines. RI guidance should be followed in performing the remedial investigation. The following items are of particular importance to risk assessments. If the risk assessment is being prepared as a stand-alone document, the following items should be included. If, instead, the risk assessment is a section of the RI Report, the items which follow should be addressed in the RI Report and clearly referenced in the Baseline Risk Assessment Report.

- Present a general map of the site depicting boundaries and surface topography, which illustrates site features, such as fences, ponds, structures, as well as geographical relationships between potential receptors and the site.
- Discuss historical site activity.
- Discuss chronology of land use (specify agriculture, industry, recreation, waste deposition, and residential development at the site).
- Present an overview of the nature and extent of contamination, including when samples were collected and the kinds of contaminants and media potentially contaminated.
- Describe the analytical and data validation methods used.
- If modeling was used to estimate exposure point concentrations, document the parameters related to soil/sediment, hydrogeology, hydrology, and meteorology either in the risk assessment or the RI Report.

Risk Assessment Guidelines. The risk assessment should be conducted in accordance with all appropriate guidance and policies. Consult with your EPA regional risk assessor regarding the most appropriate guidance.

Interim Deliverables should be prepared as described in Chapter 3.1.1 and should ultimately be incorporated into the Baseline Risk Assessment Report. The Interim Deliverables prepared by the risk assessment author should be reviewed by the EPA risk assessor prior to submission of the Baseline Risk Assessment Report. Hazard identification and exposure parameters, among others, may require discussion, refinement, and revision. Review and modification of Interim Deliverables will greatly reduce the Baseline Risk Assessment Report preparation and review time. Discussions of the three categories of risk assessment deliverables (Interim Deliverables, Draft Baseline Risk Assessment Report, and Final Baseline Risk Assessment Report) follow. Transfer of risk assessment data to the CERCLIS 3 database is also addressed.

3.1 INTERIM DELIVERABLES

This section presents an outline of the Standard Tables, Worksheets, and Supporting Information that should be prepared as Interim Deliverables for each site. The Workplan discussed in Chapter 2.2.1 should also describe the Standard Tables, Worksheets, and Supporting Information for a particular site. Exhibit 3-1 presents a list of the Interim Deliverables. Use of these deliverables for each site should improve standardization in risk assessment reporting by improving the transparency, clarity, consistency, and reasonableness of risk assessments.

3.1.1 STANDARD TABLES, WORKSHEETS, AND SUPPORTING INFORMATION

Standardized reporting of Superfund human health risk assessments will be achieved through the preparation of Standard Tables, Worksheets, and Supporting Information. These documents should be prepared as Interim Deliverables and reviewed by the EPA risk assessor prior to preparation of the Baseline Risk Assessment Report. After review and revision, as necessary, these documents should be included in the Baseline Risk Assessment Report.

This section describes the ten Standard Table formats for use in all future risk assessments. The Standard Table formats can not be altered (i.e., columns can not be added, deleted, or changed); however, rows and footnotes can be added as appropriate. Standardization of the Tables is needed to achieve Superfund program-wide reporting consistency and to accomplish electronic data transfer to the Superfund database. Note that multiple versions of some Standard Tables may be needed to address different Media, different Exposure Pathways, or different Exposures (i.e., reasonable maximum exposure [RME] versus central tendency [CT]). Exhibit 3-2 summarizes the relationship between five traditional risk assessment activities and the corresponding Standard Tables that standardize risk assessment reporting. The five risk assessment activities follow:

- Data collection
- Data evaluation
- Exposure assessment
- Toxicity assessment
- Risk characterization.

Copies of the blank Standard Tables are provided in both LOTUS® and Excel® spreadsheet formats on the electronic media enclosed with Part D guidance. Blank Standard Table templates and completed examples of typical
Standard Tables are provided in Appendix A. Detailed Instructions for the completion of the Standard Tables are provided in Appendix B.

In addition to the Standard Tables, a Data Useability Worksheet is provided in Exhibit 3-3 in this chapter, as well as in Appendix C and on the electronic media. Worksheets to document Lead and Radionuclide risk calculations are under development and will be provided in a future update to Part D. Use of the Worksheets is strongly encouraged to improve transparency, clarity, consistency, and reasonableness.

The Standard Tables and Worksheets document the majority of the data and assumptions used to evaluate risk, as well as the risks and hazards calculated. In most cases, other data and rationale are used to support the information presented in the Standard Tables. This additional Supporting Information should also be provided to the EPA risk assessor as an Interim Deliverable and later incorporated in the Baseline Risk Assessment Report.

Descriptions of the Standard Tables, Worksheets, and Supporting Information follow:

STANDARD TABLE 1: Selection of Exposure Pathways. The purposes of **Standard Table 1** are:

- To assist in project planning
- To accompany the site conceptual model
- To present possible Receptors, Exposure Routes, and Exposure Pathways
- To present the rationale for selection or exclusion of each Exposure Pathway
- To communicate risk information to interested parties outside EPA.

The information documented in **Standard Table 1** includes:

- Exposure Pathways that were examined and excluded from analysis
- Exposure Pathways that will be evaluated qualitatively or quantitatively in the risk assessment.

The data elements presented in **Standard Table 1** are listed in the Standard Table 1 highlight box.

Perform the following steps associated with the preparation of **Standard Table 1**:

1. Refine site conceptual model which identifies all potential sources of contamination, all potential Exposure Pathways, the Medium associated with

each, and the potentially exposed populations (Receptors).

2. Select realistic Exposure Pathways for detailed analyses.

3. Include rationale for exclusion of potential Exposure Pathways.

4. **Modify Standard Table 1, if necessary.**

5. **Standard Table 1** should later be incorporated in the Baseline Risk Assessment Report.

DATA ELEMENTS IN
STANDARD TABLE 1

Provide the following information: Scenario Timeframe, Medium, Exposure Medium, Exposure Point, Receptor Population, Receptor Age, Exposure Route, On-site/Off-site, Type of Analysis, Rationale for Selection or Exclusion of Exposure Pathway.

DATA USEABILITY WORKSHEET. Data quality is an important component of the risk assessment and the evaluation of data quality should be documented. The Data Useability Worksheet is included to address this need.

The EPA risk assessor and the EPA document *Guidance for Data Useability in Risk Assessment (Part A,* EPA 1990a*),* should be consulted before completing the Data Useability Worksheet. This Worksheet should be prepared as soon as all data validation reports have been completed for each medium. A media-specific Data Useability Worksheet should be completed only after the project team (i.e., lead chemist, lead hydrogeologist, risk assessor, etc.) has collectively discussed the data useability criteria. The Worksheet should be used to record and identify the impact of data quality issues as they relate to data useability. For example, deviations from approved site Workplans which occurred during sample collection, laboratory analysis, or data review should be assessed. Also refer to your regional office for guidance on data validation when preparing the Worksheet.

- **Complete the Data Useability Worksheet** for each Medium prior to screening of chemicals of potential concern (COPCs).
- The **Data Useability Worksheet** should later be incorporated in the Baseline Risk Assessment Report.

STANDARD TABLE 2: Occurrence, Distribution, and Selection of COPCs. The purposes of **Standard Table 2** are:

- To provide information useful for data evaluation of chemicals detected
- To provide adequate information so the user/reviewer gets a sense of the chemicals detected at the site and the potential magnitude of the potential problems at the site
- To provide chemical screening data and rationale for selection of COPCs.

The information documented in **Standard Table 2** includes:

- Statistical information about chemicals detected in each Medium
- The detection limits of chemicals analyzed
- The toxicity screening values for COPC selection
- The chemicals selected and deleted as COPCs.

The data elements presented in **Standard Table 2** are listed in the Standard Table 2 highlight box.

Perform the following steps associated with the preparation of **Standard Table 2**. Refer to the regional office for guidance when performing these steps.

DATA ELEMENTS IN
STANDARD TABLE 2

For each unique combination of Scenario Timeframe, Medium, Exposure Medium, and Exposure Point, provide the following information: CAS Number, Chemical, Minimum Concentration, Minimum Qualifier, Maximum Concentration, Maximum Qualifier, Units, Location of Maximum Concentration, Detection Frequency, Range of Detection Limits, Concentration Used for Screening, Background Value, Screening Toxicity Value, Potential ARAR/TBC Value, Potential ARAR/TBC Source, COPC Flag, Rationale for Contaminant Deletion or Selection.

1. Discuss selection criteria for COPCs; including toxicity screening values, frequency of

detection, and background comparison.

2. Perform screening; select COPCs that will be carried into the risk assessment (include comparison to regulatory standards and criteria where appropriate).

3. Use background information to determine COPCs, as appropriate.

4. **Submit Supporting Information to substantiate the available Background value shown for each chemical in Standard Table 2** and to enable verification of those values by EPA. The format of the summary will be determined by each region. The Supporting Information should provide relevant information for each chemical used to determine the background concentration, including (but not limited to) average, maximum, hypothesis testing of equality of the mean, upper tolerance limit (UTL) derivation, and other information that may be required to fully describe the background selection process.

5. The Background Supporting Information should later be incorporated in the Baseline Risk Assessment Report.

6. **Complete Standard Table 2** for each combination of Scenario Timeframe, Medium, Exposure Medium, and Exposure Point.

7. **Standard Table 2** should later be incorporated in the Baseline Risk Assessment Report.

STANDARD TABLE 3: Medium-Specific Exposure Point Concentration (EPC) Summary. The purposes of **Standard Table 3** are:

- To provide the reasonable maximum and central tendency medium-specific EPCs for measured and modeled values
- To provide statistical information on the derivation of the EPCs.

The information documented in **Standard Table 3** includes:

- Statistical information which was used to calculate the Medium EPCs for chemicals detected in each medium
- The RME Medium EPC and the CT Medium EPC selected
- The statistics which were used to make the determinations as well as the rationale for the selection of the statistics for each chemical (i.e., discuss statistical derivation of measured data or approach for modeled data).

The data elements presented in **Standard Table 3** are listed in the Standard Table 3 highlight box.

DATA ELEMENTS IN
STANDARD TABLE 3

For each unique combination of Scenario Timeframe, Medium, Exposure Medium, and Exposure Point, provide the following information: Chemical of Potential Concern, Units, Arithmetic Mean, 95% upper confidence level (UCL) of Normal Data, Maximum Detected Concentration, Maximum Qualifier, EPC Units, Reasonable Maximum Exposure (Medium EPC Value, Medium EPC Statistic, and Medium EPC Rationale), and Central Tendency (Medium EPC Value, Medium EPC Statistic, and Medium EPC Rationale).

Perform the following steps associated with the preparation **of Standard Table 3**.

1. Discuss how samples will be grouped (e.g., how hot spots in soil will be considered; how groundwater data will be combined; how temporal and chemical phases will be addressed; how upgradient, downgradient, and cross gradient samples will be addressed).

2. Discuss approach to determine how data are normally or log-normally distributed.

3. Discuss evaluation of lead, total chromium and any other special chemicals.

4. **Submit Supporting Information to document the EPC summary presented in Standard Table 3** and to enable verification of those values by EPA. The format of the summary will be determined by each region. The Supporting Information should discuss media-specific EPCs statistically derived from

measured data, including identification of the samples used in each calculation, results of distribution testing (Wilk-Shapiro, D'Agostino), mean (transformed if appropriate), maximum (transformed if appropriate), standard deviation (transformed if appropriate), t- or H-statistic, 95% UCL (including non-parametric methods, where applicable), and other protocols as required. The Supporting Information should also present information for route-specific EPCs, including derivation of modeled values, assumptions and values used, statistical derivation of measured values and associated calculations, and other protocols as required. These route-specific EPCs should be presented in Standard Table 7.

5. The **EPC Supporting Information** should later be incorporated in the Baseline Risk Assessment Report.

6. **Complete Standard Table 3** for each combination of Scenario Timeframe, Medium, Exposure Medium, and Exposure Point.

7. **Standard Table 3** should later be incorporated in the Baseline Risk Assessment Report.

STANDARD TABLE 4: Values Used for Daily Intake Calculations. The purposes of **Standard Table 4** are:

- To provide the exposure parameters used for RME and CT intake calculations for each Exposure Pathway (Scenario Timeframe, Medium, Exposure Medium, Exposure Point, Receptor Population, Receptor Age, and Exposure Route)
- To provide the intake equations or models used for each Exposure Route/Pathway.

The information documented in **Standard Table 4** includes:

- Values used for each intake equation for each Exposure Pathway and the reference/rationale for each
- Intake equation or model used to calculate the intake for each Exposure Pathway.

The data elements presented in **Standard Table 4** are listed in the Standard Table 4 highlight box.

DATA ELEMENTS IN STANDARD TABLE 4

For each unique combination of Scenario Timeframe, Medium, Exposure Medium, Exposure Point, Receptor Population, and Receptor Age, provide the following information: Exposure Route, Parameter Code, Parameter Definition, Units, RME Value, RME Rationale/Reference, CT Value, CT Rationale/Reference, and Intake Equation/Model Name.

Perform the following steps associated with the preparation of **Standard Table 4**.

1. Provide references for all exposure parameters.

2. **Submit Supporting Information to summarize the Modeled Intake Methodology and Parameters used to calculate modeled intake values** and to enable verification of those values by EPA. The Supporting Information should be limited to summary level information. The format of the summary should be structured to accommodate the variability and complexity associated with different models.

3. The **Modeled Intake Supporting Information** should later be incorporated in the Baseline Risk Assessment Report.

4. **Submit Supporting Information on Chemical-Specific Parameters**, which apply to all Standard Tables to be completed for the risk assessment and to enable verification of those values by EPA. The summary should identify and display chemical parameters and constants that are used to calculate risks and hazards, but are not included on Standard Tables. The format of the summary will be determined by each region. The values and constants that are used to calculate risk and hazards, including molecular weight, vapor pressure, K_{oc}, K_{ow}, dermal permeability constant, Henry's Law constant, and other information that the reader would find useful for understanding the risk assessment

discussion should be included.

5. The **Chemical-Specific Parameter Supporting Information** summary should later be incorporated into the Baseline Risk Assessment Report.

6. **Complete Standard Table 4** for each combination of Scenario Timeframe, Medium, Exposure Medium, Exposure Point, Receptor Population, and Receptor Age.

7. **Standard Table 4** should later be incorporated into the Baseline Risk Assessment Report.

STANDARD TABLES 5 AND 6: Non-Cancer and Cancer Toxicity Data. The purposes of **Standard Tables 5.1, 5.2, and 5.3** are:

- To provide information on reference doses (RfDs) target organs, and adjustment factors for chemicals
- To provide oral to dermal adjustment factors
- To verify references for non-cancer toxicity data
- To provide non-cancer toxicity information for "special-case" chemicals.

The information documented in **Standard Tables 5.1, 5.2, and 5.3** includes:

- The RfDs for each of the COPCs, as well as modifying factors and reference concentration (RfC) to RfD adjustments
- The organ effects of each of the COPCs
- References for RfCs and organ effects.

The data elements presented in **Standard Tables 5.1, 5.2, and 5.3** are listed in the Standard Tables 5.1, 5.2, and 5.3 highlight box.

DATA ELEMENTS IN
STANDARD TABLE 5.1

Provide the following information: Chemical of Potential Concern, Chronic/Subchronic, Oral RfD Value, Oral RfD Units, Oral to Dermal Adjustment Factor, Adjusted Dermal RfD, Units, Primary Target Organ, Combined Uncertainty/Modifying Factors, Sources of RfD:Target Organ, and Dates of RfD:Target Organ.

DATA ELEMENTS IN
STANDARD TABLE 5.2

Provide the following information: Chemical of Potential Concern, Chronic/Subchronic, Value Inhalation RfC, Units, Adjusted Inhalation RfD, Units, Primary Target Organ, Combined Uncertainty/Modifying Factors, Sources of RfC:RfD:Target Organ, and Dates.

DATA ELEMENTS IN
STANDARD TABLE 5.3

Provide the following information: Chemical of Potential Concern, Chronic/Subchronic, Value, Units, Primary Target Organ, Combined Uncertainty/Modifying Factors, Sources of Toxicity:Primary Target Organ, and Date.

The purposes of **Standard Tables 6.1, 6.2, and 6.3** are:

- To provide the oral, dermal, and inhalation cancer toxicity information (values and sources of information) for chemicals of potential concern

- To provide the methodology and adjustment factors used to convert oral cancer toxicity values to dermal toxicity values and to convert inhalation unit risks to inhalation cancer slope factors
- To provide weight of evidence/cancer guideline descriptions for each chemical of potential concern
- To provide cancer toxicity information for "special case" chemicals.

The information documented in **Standard Tables 6.1, 6.2, and 6.3** includes:

- Oral, dermal, and inhalation toxicity values for chemicals of potential concern
- Weight of evidence/cancer guidelines descriptions for chemicals of potential concern
- The source/reference for each toxicity value.

The data elements presented in **Standard Tables 6.1, 6.2, and 6.3** are listed in the Standard Tables 6.1, 6.2, and 6.3 highlight box.

Perform the following steps associated with the preparation of **Standard Tables 5 and 6.**

1. Ensure that chronic and subchronic toxicity values are applied correctly based on the duration of exposure. Provide rationale for selection of surrogate toxicity values not in IRIS or HEAST, or provided by NCEA.

DATA ELEMENTS IN STANDARD TABLE 6.1

Provide the following information: Chemical of Potential Concern, Oral Cancer Slope Factor, Oral to Dermal Adjustment Factor, Adjusted Dermal Cancer Slope Factor, Units, Weight of Evidence/Cancer Guideline Description, Source, and Date.

DATA ELEMENTS IN STANDARD TABLE 6.2

Provide the following information: Chemical of Potential Concern, Unit Risk, Units, Adjustment, Inhalation Cancer Slope Factor, Units, Weight of Evidence/Cancer Guideline Description, Source, and Date.

DATA ELEMENTS IN STANDARD TABLE 6.3

Provide the following information: Chemical of Potential Concern, Value, Units, Source, and Dates.

2. **Submit Supporting Information regarding Toxicity Data for Special Case Chemicals** (i.e., those chemicals with cancer risks and non-cancer hazards calculated using methods or toxicity parameters different from those presented on Standard Tables 5.1, 5.2, 6.1, or 6.2). The Supporting Information will be used to enable verification of those values by EPA. Examples include selection of potency factors for polychlorinated biphenyls (PCBs), use of relative potencies for polynuclear aromatic hydrocarbons (PAHs) and chlorinated dioxins and furans, and valence species assumptions for metals.

3. The **Special Case Chemicals Supporting Information** should later be incorporated in the Baseline Risk Assessment Report.

4. Refer to the end of Chapter 3.1.1 for instructions for lead and radionuclides.

5. **Complete Standard Tables 5 and 6** for the exposure routes and chemicals under evaluation.

   Standard Table 5.1: Non-Cancer Toxicity Data - Oral/Dermal
   Standard Table 5.2: Non-Cancer Toxicity Data - Inhalation
   Standard Table 5.3: Non-Cancer Toxicity Data - Special Case Chemicals

   Standard Table 6.1: Cancer Toxicity Data - Oral/Dermal
   Standard Table 6.2: Cancer Toxicity Data - Inhalation
   Standard Table 6.3: Cancer Toxicity Data - Special Case Chemicals.

6. **Standard Tables 5 and 6** should later be incorporated in the Baseline Risk Assessment Report.

STANDARD TABLES 7 AND 8: Calculation of Non-Cancer Hazards and Cancer Risks. The purposes of **Standard Tables 7 and 8** are:

- To provide a summary of the variables used to calculate non-cancer hazards and cancer risks
- To show the EPC (medium-specific or route-specific) and intake used in the non-cancer hazard and cancer risk calculations
- To present the result of the calculation for each Exposure Route/Pathway for each COPC
- To provide the total hazard index and cancer risks for all Exposure Routes/Pathways for the Scenario Timeframe, Exposure Medium, and Receptor presented in this table.

The information documented in **Standard Tables 7 and 8** includes:

- The non-cancer hazard quotient (HQ) and cancer risk value for each COPC for each Exposure Route/ Pathway
- The values used for EPC, non-cancer intake, cancer intake, reference doses and

concentrations, and cancer slope factor for each COPC for each Exposure Route.

The data elements presented in **Standard Tables 7 and 8** are listed in the Standard Tables 7 and 8 highlight boxes.

Perform the following steps associated with the preparation of **Standard Tables 7 and 8**.

1. Address non-cancer hazards and cancer risks including the calculations and supporting information by Exposure Route.

DATA ELEMENTS IN STANDARD TABLE 7

For each unique combination of Scenario Timeframe, Medium, Exposure Medium, Exposure Point, Receptor Population, and Receptor Age, provide the following information: Exposure Route, Chemical of Potential Concern, Medium EPC Value, Medium EPC Units, Route EPC Value, Route EPC Units, EPC Selected for Hazard Calculation, Intake (Non-Cancer), Intake (Non-Cancer) Units, Reference Dose, Reference Dose Units, Reference Concentration, Reference Concentration Units, and Hazard Quotient.

2. Include RME and CT results. Ensure that risks and hazards from multiple chemicals are combined appropriately across Pathways that affect the same individual or population subgroup, for all site-related chemicals.

3. Definitions of Standard Tables
   Standard Table 7.n.RME: Calculation of Non-Cancer Hazards (RME)
   Standard Table 7.n.CT: Calculation of Non-Cancer Hazards (CT)
   Standard Table 8.n.RME: Calculation of Cancer Risks (RME)
   Standard Table 8.n.CT: Calculation of Cancer Risks (CT)

4. **Submit Supporting Information that summarizes the approach used to perform Special Chemical Risk and Hazard Calculations** and to enable verification of those values by EPA. This summary should address the calculation of non-cancer hazards and cancer risks for chemicals that do not use RfD or cancer slope factor (CSF) values, respectively. The format of the summary will be determined by each region.

DATA ELEMENTS IN STANDARD TABLE 8

For each unique combination of Scenario Timeframe, Medium, Exposure Medium, Exposure Point, Receptor Population, and Receptor Age, provide the following information: Exposure Route, Chemical of Potential Concern, Medium EPC Value, Medium EPC Units, Route EPC Value, Route EPC Units, EPC Selected for Risk Calculation, Intake (Cancer), Intake (Cancer) Units, Cancer Slope Factor, Cancer Slope Factor Units, and Cancer Risk.

5. The **Special Chemical Risk and Hazard Calculations Supporting Information** should later be incorporated in the Baseline Risk Assessment Report.

6. **Complete Standard Tables 7 and 8** for each combination of Scenario Timeframe, Medium, Exposure Medium, Exposure Point, Receptor Population, and Receptor Age.

7. **Standard Tables 7 and 8** should later be incorporated in the Baseline Risk Assessment Report.

STANDARD TABLES 9 AND 10: Risks and Hazards. The purpose of **Standard Table 9** is:

- To provide a summary for each Receptor, by Medium, Exposure Route, and Exposure Point, of cancer risks and non-cancer hazards.

The purpose of **Standard Table 10** is:

- To provide a summary for each Receptor, by Medium, Exposure Route, and Exposure Point, of cancer risks and non-cancer hazards that may trigger the need for remedial action.

The information documented in **Standard Tables 9 and 10** includes:

- The cancer risk and non-cancer hazard to each Receptor for each COPC by Exposure Route and Exposure Point
- The total cancer risk and non-cancer hazard for each Exposure Pathway
- The total cancer risk and non-cancer hazard for each Medium across all Exposure Routes
- The primary target organs for non-carcinogenic hazard effects.

The data elements presented in **Standard Tables 9 and 10** are listed in the Standard Tables 9 and 10 highlight boxes.

DATA ELEMENTS IN STANDARD TABLE 9

For each unique combination of Scenario Timeframe, Receptor Population, and Receptor Age, provide the following information: Medium, Exposure Medium, Exposure Point, Chemical, Carcinogenic Risk (Ingestion, Inhalation, Dermal, and Exposure Routes Total), Chemical, and Non-Carcinogenic Hazard Quotient (Primary Target Organ, Ingestion, Inhalation, Dermal, and Exposure Routes Total).

DATA ELEMENTS IN STANDARD TABLE 10

For each unique combination of Scenario Timeframe, Receptor Population, and Receptor Age, provide the following information: Medium, Exposure Medium, Exposure Point, Chemical, Carcinogenic Risk (Ingestion, Inhalation, Dermal, and Exposure Routes Total), Chemical, and Non-Carcinogenic Hazard Quotient (Primary Target Organ, Ingestion, Inhalation, Dermal, and Exposure Routes Total).

Perform the following steps associated with the preparation of **Standard Tables 9 and 10**.

1. Address non-cancer hazards and cancer risks including the calculations and supporting information by Exposure Route.

2. Include RME and CT results. Ensure that risks and hazards from multiple chemicals are combined appropriately across Pathways that affect the same individual or population subgroup, for all site-related chemicals.

3. Definitions of Standard Tables
   Standard Table 9.n.RME: Summary of Receptor Risks and Hazards for COPCs (RME)
   Standard Table 9.n.CT: Summary of Receptor Risks and Hazards for COPCs (CT)
   Standard Table 10.n.RME: Risk Assessment Summary (RME)
   Standard Table 10.n.CT: Risk Assessment Summary (CT)

4. **Complete Standard Tables 9 and 10** for each combination of Scenario Timeframe, Receptor Population, and Receptor Age.

5. **Standard Tables 9 and 10** should later be incorporated in the Baseline Risk Assessment Report.

LEAD AND RADIONUCLIDES WORK-SHEETS. Perform the following steps associated with the preparation of **Lead and Radionuclides Worksheets**:

1. For lead, **complete the Lead Worksheets** for Screening Analysis, Child, and Adult **(to be developed)**. Also attach the appropriate graphs and results from the Integrated Exposure Uptake Biokinetic Model (IEUBK) model to the Child Worksheet.

2. For radionuclides, **complete the Radionuclide Worksheet (to be developed)**.

3. The **Lead and Radionuclide Worksheets** should later be incorporated in the Baseline Risk Assessment Report.

3.1.2 ASSESSMENT OF CONFIDENCE AND UNCERTAINTY

Uncertainty assessment is important in risk assessment. Although the risk assessment should indicate sources of variability and uncertainty

throughout the process, it will generally be appropriate to include a separate section of the Baseline Risk Assessment Report that also focuses on the uncertainties associated with data evaluation, toxicity assessment, exposure assessment, and risk characterization, as well as overall uncertainty of the final risk numbers. The region may choose to defer presentation of this specific section to the Draft Baseline Risk Assessment Report.

Summarize the Assessment of Confidence and Uncertainty. The Assessment of Confidence and Uncertainty should later be incorporated in the Baseline Risk Assessment Report.

3.1.3 PROBABILISTIC ANALYSIS INFORMATION

Based upon the results from a deterministic risk characterization calculation (Standard Tables 7 and 8), a decision should be made if a Probabilistic Analysis will be performed to calculate cancer risks and non-cancer hazards in accordance with Agency policy. If Probabilistic Analysis is performed, the information which follows should be addressed:

- The results from the initial evaluations (deterministic and sensitivity analyses) should be evaluated along with any additional exposure information to determine whether a Probabilistic Analysis is feasible.

- For those parameters determined in the initial evaluations to have the most uncertainty (described in Chapter 3.1.2) proceed to the Probabilistic Analysis. For this analysis, provide the exposure parameter distributions, their source and rationale for selection, and indicate which parameters are correlated. Indicate pertinent information such as the model to be used for the analysis, type of software, exposure equations, number of iterations, etc. The results of the Probabilistic Analysis should be presented as either a chapter in the Baseline Risk Assessment Report or as an appendix in accordance with regional preferences.

- As part of the Risk Characterization portion of the Baseline Risk Assessment Report, present a summary of the Probabilistic Analysis results including graphic displays, the CT and RME values, and a qualitative discussion of the results of the analysis and the representativeness of distribution data for the population of concern.

- The uncertainty associated with the CT and RME values, population risks, if appropriate, and the uncertainty associated with the Probabilistic Analysis should be summarized in the Risk Characterization section of the Baseline Risk Assessment Report.

- **Summarize the Probabilistic Analysis (if performed)**.

- The **Probabilistic Analysis** summary should will later be incorporated in the Baseline Risk Assessment Report.

3.2 DRAFT BASELINE RISK ASSESSMENT REPORT

Submit the Draft Baseline Risk Assessment Report after the completion and acceptance of the Interim Deliverables described above. EPA guidance should be consulted in preparing the Draft Baseline Risk Assessment Report. EPA anticipates that this report preparation will be greatly expedited, since it should incorporate the following Interim Deliverables:

- Standard Tables 1 through 10
- Worksheets on Data Useability, Lead and Radionuclides, as applicable
- Supporting Information
- The Assessment of Confidence and Uncertainty
- Probabilistic Analysis information.

However, the report should not consist exclusively of the Interim Deliverables, since additional narrative will be necessary for a clear and comprehensible Baseline Risk Assessment Report. For example, information such as definition of hazard indices and cancer slope factors, Toxicological Profiles for COPCs, and other information indicated by risk assessment guidance should be incorporated.

Risk assessments submitted to the Agency or

performed by the Agency should incorporate any current Agency guidance applicable on Risk Characterization.

3.3 FINAL BASELINE RISK ASSESSMENT REPORT

Submit the Final Baseline Risk Assessment Report as a revision of the draft, incorporating review comments as necessary and appropriate.

3.4 DATA TRANSFER TO CERCLIS 3

Upon the completion of the Final Baseline Risk Assessment Report, use the LOTUS® or EXCEL® version of the Standard Tables to **transfer summary level risk data to the CERCLIS 3 database.**